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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,348	08/15/2003	Keith K. Daellenbach	BJT 332B	1593

23581 7590 08/10/2007

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EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
08/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/642,348	DAELLENBACH, KEITH K.	
	Examiner	Art Unit	
	Laura C. Schell	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-20,23 and 27-31* is/are pending in the application.

4a) Of the above claim(s) *18-20,27,28,30 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13-17,23,29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/13/07-7/30/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 and consequently dependent claims 2-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As pointed out in the previous rejection, there is not support for the words "about 643 psig" and "about 2001 psig". The words "about" have not been found in the specification in conjunction with the pressures claimed. The addition of these words to the claims change the scope of the claimed range and the range supported by the specification. Therefore the addition of the words "about" is considered new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Menne et al. (US Patent No. 5,840,061). Menne discloses a needle-free jet injection device (Fig. 3) for delivering a fluid into an internal organ, the device comprising: a rigid end effector (9) having a blunt distal end (distal end near 17 is blunt) and including at least one injection orifice (2) disposed on a sidewall of the end effector, the end effector having a longitudinal axis configured into a shape wherein the end effector is sufficiently rigid to maintain the shape of its longitudinal axis during use (fig. 3); the longitudinal axis of the lend effector being substantially straight (Fig. 3), wherein the at least one injection orifice is oriented generally laterally to the longitudinal axis of the end effector (orifice 2 is on the lateral side of the end effector); a fluid reservoir (the fluid reservoir is connected at 19 as described in col. 5, lines 7-8); and an ejection mechanism (Fig. 1, 4 is the piston/ejection mechanism) adapted to eject the fluid from the fluid reservoir through the end effector and out of the injection orifice at high pressures (col. 1, lines 50-55). Menne further discloses that the device injects the fluid at high penetration depths and with minimum tissue damage (col. 6, lines 41-42). Menne, however, does not disclose the pressures at which the fluid is injected. It would have been obvious to

one of ordinary skill in the art at the time of the invention to have modified Menne to use the device to produce the claimed optimum range of pressures of 643-2001 psig, since Menne discloses that the injection pressure it uses minimizes tissue damage (col. 6, lines 41-42) and since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

In reference to claim 6, Menne discloses that the ejection mechanism is further adapted to allow the device to eject multiple doses of fluid without refilling the fluid reservoir (col. 5, lines 44-49).

In reference to claim 23, Menne discloses that the shape of the longitudinal axis of the end effector is generally straight (Fig. 3).

Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menne et al. (US Patent No. 5,840,061) in view of Paskar (6,623,449). In reference to claims 2-5, Menne discloses the device substantially as claimed; including a rigid end effector (Fig. 3) and an injection orifice (2) located in the distal section of the straight shaft (Fig. 3), however, Menne does not disclose that the end effector includes a plurality of injection orifices. Paskar, however, discloses a jet injection system (Fig. 16) which has a plurality of injection orifices (134) located at the distal section. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to

have modified Menne with the plurality of injection orifices, as taught by Paskar; in order to be able to treat the entire prostate and for a faster procedure.

Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menne et al. (US Patent No. 5,840,061) in view of Paskar (6,623,449). Menne discloses the device substantially as claimed including an injection orifice (2), however Menne does not disclose that the injection orifices are arranged linearly or in multiple offset rows. Paskar, however, discloses a jet injector system (Fig. 16) which includes injection orifices (134) arranged linearly and in multiple offset rows along the length of the end effector. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Menne with the plurality of injection orifices and the arrangement of the orifices, as taught by Paskar, in order to provide an end effector that can treat a greater surface area of tissue without missing portions of the tissue to be treated, thus creating a shorter treatment time.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Menne et al. (US Patent No. 5,840,061) in view of Glines et al. (US Patent No. 6,716,190). Menne discloses the device substantially as claimed, including that it delivers fluid to the prostate (col. 5, lines 14-16), however, Menne does not disclose that it delivers ethanol. Glines, however, discloses a needle-free jet injection device which delivers ethanol (col. 18, lines 29-32). Therefore it would have been obvious to one of ordinary skill in the art to have used the needle-free jet injection device of Nash to deliver ethanol, as taught by

Glines, because ethanol is fluid that is particularly useful to inject into tissues, particularly to ablate a tissue at the site of the jet injector.

Claims 11, 13-17 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menne et al. (US Patent No. 5,840,061) in view of Glines et al. (US Patent No. 6,716,190). Menne discloses a needle-free jet injection device (Fig. 3) for delivering a fluid into an internal organ the device comprising: a fluid reservoir (the fluid reservoir is connected at 19 as described in col. 5, lines 7-8); a longitudinally rigid extension structure (Fig. 3, 9) adapted to be positioned so that a distal region of the extension structure is positioned adjacent the internal organ (col. 5, lines 10-20), wherein the distal region of the extension has an at least partially hollow interior (1) that fluidly communicates with the fluid reservoir (via 10 and 19), wherein the extension structure is sufficiently rigid to maintain a longitudinal shape during use, wherein the distal region has a blunt distal area (distal end near 17 is blunt) and the longitudinal shape of the extension structure is substantially straight (9 is straight as seen in Fig. 3); and an ejection mechanism (4 in Fig. 1 is the piston/ejection mechanism) adapted to eject the fluid from the fluid reservoir through the extension structure and out of an injection orifice (2) provided in a sidewall of the distal region of the extension structure (fig. 3) with sufficient pressure to penetrate the internal organ while preserving functionality of the internal organ (col. 6, lines 41-42), wherein the ejection mechanism comprises a plunger (4) powered pneumatically (col. 2, lines 37-40 and col. 4, lines 35-

37), wherein the orifice is oriented in a direction generally lateral to the longitudinal axis of the extension structure (Fig. 3).

Menne, however, does not disclose that the extension structure includes a plurality of orifices or the ejection mechanism being a plunger powered by a gas cartridge. Glines, however, discloses a jet injection system with an end effector that has a plurality of jet injection orifices arranged in the side wall of the end effector (Fig. 12) as well as a jet injection system with an end effector that has a plurality of jet injection orifices arranged at the distal end (Fig. 8c). Glines further discloses that the needle-free jet injection device has an ejection mechanism that powered by a gas cartridge (col. 4, line 59 through col. 5, line 9). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Menne with the plurality of orifices and the ejection mechanism powered by a gas cartridge, as taught by Glines, in order to provide an end effector that is capable of treating a larger surface area of the prostate in one treatment, in order to provide a faster treatment as well as to provide a high-pressure power source to deliver the fluid into the tissue at a high pressure with out the need of a needle (abstract), especially since Menne discloses that the plunger can be driven pneumatically.

In reference to claim 13, Menne discloses the device substantially as claimed, including that it delivers fluid to the prostate (col. 5, lines 14-16), however, Menne does not disclose that it delivers ethanol. Glines, however, discloses a needle-free jet injection device which delivers ethanol (col. 18, lines 29-32). Therefore it would have been obvious to one of ordinary skill in the art to have used the needle-free jet injection

device of Nash to deliver ethanol, as taught by Glines, because ethanol is fluid that is particularly useful to inject into tissues, particularly to ablate a tissue at the site of the jet injector.

In reference to claims 14-17 and 29, Menne discloses the device substantially as claimed including an injection orifice (2), however, Menne does not disclose a plurality of injection orifices arranged in offset rows or that the gas cartridge is a replaceable carbon dioxide cartridge. Glines, however, discloses that the injection orifices (Fig. 14a and 14b, 422) are arranged linearly in multiple offset rows along the length of the end effector, and that they are oriented in a direction generally lateral to a longitudinal axis of the distal region of the extension structure (Figs. 14a and 14b). Glines further discloses that the gas cartridge is a replaceable carbon dioxide cartridge (col. 4, lines 64-65). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Menne with the arrangement of the plurality of orifices, as taught by Glines, in order to provide an end effector that is capable of treating a larger surface area, without missing portions of the prostate, which would be avoided with the offset rows, in order to provide a more efficient treatment and provide a medically safe gas to power the injections.

Response to Amendment

The declaration under 37 CFR 1.132 filed 1/23/2007 is sufficient to overcome the rejection of claims1, 6, 7 and 23 based upon Hauschild et al. (US 6905475).

Response to Arguments

Applicant's arguments with respect to claims 1-11, 13-17, 23 and 29 have been considered but are moot in view of the new ground(s) of rejection.

In response to Applicant's request that the withdrawal of claims 18-20, 27, 28, 30 and 31 be reconsidered, it is the examiner's position that withdrawing the above named claims should be maintained. Not only has applicant received an election/restriction requirement, in which applicant elected to have species C examined, but the amendments to claims 1, 11 and 18 clearly point out the fact that Applicant is now directing claims 1, 11 and 18 to different embodiments (claims 1 and 11 are now drawn to a needle-free jet injection device with an explicitly straight shaft/longitudinal axis, while claim 18 is now drawn to a needle-free jet injection device with a portion of the distal shaft being angled to the rest of the shaft/longitudinal axis, which clearly indicate two different species/embodiments). Therefore the withdrawal of the claims will be maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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